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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,382	06/15/2001	Wan S. Lee	1408.017	8310

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	10

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/882,382	LEE ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- Th MAILING DATE of this communication appears on th cov r she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time and amendment B, both filed 08/26/2003.

Claims 1-17 are included in the prosecution.

The following new ground of rejection is necessitated by applicant's amendment B, paper No. 9:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The "solution type acrylic adhesive" was not described in the specification as originally filed. Applicants only disclosed the solution as a step in the process of making the adhesive and before adding the drug, see page 13,

first and second full paragraphs of the present specification. Nowhere in the specification applicants disclosed a transdermal preparation having an adhesive layer comprising drug and solution type acrylic adhesive. On the other hand the specification teaches drying of the adhesive preparation to form an adhesive layer, see page 19, example 8.

The following rejection are discussed in details in the previous office action, and maintained for reasons of record:

(1) Claim Rejections - 35 USC § 102

(A) Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,035,894 ('894).

The instant claim 1 recites a transdermal preparation having an adhesive layer comprising a hydrophilic drug or drug in the salt form and an adhesive has polyethylene oxide or polyethylene oxide monomethyl ether side chain.

US '894 disclosed a transdermal drug delivery device incorporating an adhesive composition comprising grafted polymer includes polyethylene oxide side chains which impart increased solubility of hydrophilic bioactive agents in the polymer matrix, thus, enhances the rate of release of the rate of release of the bioactive agents (abstract; col.3, lines 8-12, 23). The molecular weight of the polyethylene oxide ranges between 10-1000 with a range of 100-55 preferred (col.5, lines 6-11, 61-66). The drug used included hydrocortisone and antihistaminics in an amount up to at least 10 wt% of the

adhesive composition (col.8, lines 48-50, 62-63).

The limitations of claims 1 and 3 are met by US '894 reference.

Response to Arguments

Applicant's arguments filed 08/26/2003 have been fully considered but they are not persuasive. Applicants argue that Lee's patent does not teach acrylic adhesive.

The examiner is pointing out to col.11, lines 41-60, where the reference disclosed the acrylate adhesives including methacrylate. The reference is silent regarding the consistency of the adhesive preparation.

(B) Claims 1, 2, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,779,632 ('632).

US '632 disclosed a pressure sensitive adhesive used for transdermal pharmaceutical delivery devices comprising polyethylene oxide acrylates, disclosed by applicant in page 7, lines 1-2 as an adhesive having polyethylene oxide side chain, and any therapeutic active agent useful in transdermal delivery devices or salts of those drugs (abstract; col.10, lines 35-41; col.31, line 34; col.32, line 1). The pressure sensitive adhesive further comprising a solvent and a penetration enhancer that included oleic acid and isopropyl myristate (col.32, lines 7-20). The reference disclosed a dosage form comprising a layer of the pressure sensitive adhesive coated on a backing layer and protected with a release liner (col.31, lines 40-44).

The limitation of claims 1, 2, 16, and 17 are met by US '632 reference.

Response to Arguments

Applicant's arguments filed 08/26/2003 have been fully considered but they are not persuasive. Applicants argue that the Deitz does not teach solution type acrylate polymer and argue that the reference teaches an emulsion and does not teach the preparation of the adhesive by the solution polymerization process as applicants.

The examiner position is that the reference disclosed polyethylene oxide acrylate soluble in water, and that will form a solution (col.10, lines 31-35). The expression "comprising" of the claim language permits the presence of the oil phase, i.e. emulsion. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. preparation of the adhesive by solution polymerization process) are not recited in the rejected claim(s), and the rejected claims are directed to composition not process of making. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(2) Claim Rejections - 35 USC § 103

(A) Claims 2, 4-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '894 in view of US 5,865,792 ('792).

US '894 teaches a transdermal drug delivery device incorporating an adhesive composition comprising grafted polymer includes polyethylene oxide side chains which

impart increased solubility of hydrophilic bioactive agents in the polymer matrix, thus, enhances the rate of release of the rate of release of the bioactive agents (abstract; col.3, lines 8-12, 23). The molecular weight of the polyethylene oxide ranges between 10-1000 with a range of 100-55 preferred (col.5, lines 6-11, 61-66). The drug used included hydrocortisone and antihistaminics in an amount up to at least 10 wt% of the adhesive composition (col.8, lines 48-50, 62-63).

US '894 does not teach the solvent of and the penetration enhancer of claims 2 and 7-9, any particular salt of the drug as claimed in claims 6 and 13, or the amount of the solvent, penetration enhancer and the polyethylene oxide.

US '792 teaches a device for transdermal drug delivery comprising polymeric reservoir comprising anti-inflammatory agent, solvent and penetration enhancer (abstract; col.10, line 15). The preferred anti-inflammatory agent that eliminates tissue irritation is hydrocortisone succinate (col.2, lines 50-52; col. 3, lines 13-15). The solvent includes ethanol, isopropanol, glycols such as polyethylene glycol and polypropylene glycol, and sorbitan fatty acid esters that disclosed by applicants as penetration enhancer (col.7, lines 24-33). The polymer includes polyethylene oxide blended with polyacylic acid (col.9, lines 22-31).

It is within the skill in the art to select optimal parameters such as ratios and weight percents of components in order to achieve a beneficial effect. *See In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, the ratios and weight percents of the solvent, the polyethylene oxide and the penetration enhancer instantly claimed are not considered critical absent evidence showing unexpected and superior results.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to select the hydrocortisone succinate and the suitable solvent and penetration enhancers as disclosed by US '792 to be included in the adhesive composition of a transdermal drug delivery device disclosed by US '894 and determine the amount of each ingredient according to particular need, motivated by the teaching of US '792 that the hydrocortisone succinate is the preferred anti-inflammatory drug that eliminates tissue irritation with reasonable expectation of success of the delivered transdermal drug delivery device in providing drugs in the salt forms in a controlled release manner.

(B) Claims 3, 6-11, and 13-15, rejected under 35 U.S.C. 103(a) as being unpatentable over US '632 in view of US '792.

US '632 teaches a pressure sensitive adhesive used for transdermal pharmaceutical delivery devices comprising polyethylene oxide acrylates, disclosed by the applicant in page 7, lines 1-2 as an adhesive having polyethylene oxide side chain, and any therapeutic active agent useful in transdermal delivery devices or salts of those drugs (abstract; col.10, lines 35-41; col.31, line 34; col.32, line 1). The pressure sensitive adhesive further comprising a solvent and a penetration enhancer that included oleic acid and isopropyl myristate (col.32, lines 7-20). The reference disclosed a dosage form comprising a layer of the pressure sensitive adhesive coated on a backing layer and protected with a release liner (col.31, lines 40-44).

US '632 does not teach the particular salts of the drugs as claimed in claims 6

and 13, the particular solvents of claims 7, or the amount of the drug, solvent and the penetration enhancer.

US '792 teaches a device for transdermal drug delivery comprising polymeric reservoir comprising anti-inflammatory agent, solvent and penetration enhancer (abstract; col.10, line 15). The preferred anti-inflammatory agent that eliminates tissue irritation is hydrocortisone succinate (col.2, lines 50-52; col. 3, lines 13-15). The solvent includes ethanol, isopropanol, glycols such as polyethylene glycol and polypropylene glycol, and sorbitan fatty acid esters that disclosed by applicants as penetration enhancer (col.7, lines 24-33). The polymer includes polyethylene oxide blended with polyacylic acid (col.9, lines 22-31).

It is within the skill in the art to select optimal parameters such as ratios and weight percents of components in order to achieve a beneficial effect. *See In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, the ratios and weight percents of the drug, the solvent, and the penetration enhancer instantly claimed are not considered critical absent evidence showing unexpected and superior results.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to select the hydrocortisone succinate as the drug salt and the suitable solvent as disclosed by US '792 to be included in the adhesive composition of a transdermal drug delivery device disclosed by US '632 and determine the amount of each ingredient according to particular need, motivated by the teaching of US '792 that the hydrocortisone succinate is the preferred anti-inflammatory drug that eliminates tissue irritation with reasonable expectation of success of the delivered transdermal

drug delivery device in providing drugs in the salt forms in a controlled release manner.

Response to Arguments

Applicant's arguments filed 08/26/2003 have been fully considered but they are not persuasive. Applicants argue that Le and Deitz do not teach a solution type acrylic adhesive and no suggestion in either patent that such an adhesive used for transdermal drug delivery. Ledger fails to supply this deficiency.

The examiner position is that both Lee and Deitz are directed to transdermal drug delivery devices and both disclosed the same adhesive claimed by applicants. It is expected for the same adhesive to have the same properties and consistency. Ledger's reference is relied upon for teaching the specific salts of drugs and other ingredients as solvents and enhancers. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, US '792 teaches that the hydrocortisone succinate is the preferred anti-inflammatory drug that eliminates tissue irritation. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than

by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to

5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)305-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600